REMARKS

Claims 1-2, 5-11, 16-18, 21-23, 25-29, 33 and 42-48 are pending and under consideration in the present application.

Support for the amendments *supra* can be found throughout the specification and claims as filed, for example, at original claims 1 and 16, lines 4-7 and 18-21 of page 4, lines 28-30 of page 4 continuing to lines 1-6 of page 5, lines 12-14 of page 5, lines 14-16 of page 10, and the Examples. Applicant asserts that no new matter has been added by amendment.

Applicant reserves the right to pursue any cancelled subject matter in a future application.

Issues raised in the Office Action will be addressed in the order they were raised by the Examiner.

35 U.S.C. § 112, first paragraph, enablement

Claims 1-15, 22, and 35-37 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. The Examiner states at page 2 of the Office Action that the specification is objected to under 35 U.S.C. § 112, first paragraph, as allegedly "failing to provide an adequate written description of the invention and failing to provide an enabling disclosure without complete evidence either that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of the biological materials."

Claims 3-4, 12-15 and 35-37 have been cancelled, thereby obviating the rejection with respect to these claims.

Applicant has amended the specification to include a description of the deposit of a cell line producing Alt-1 as required. A cell line which produces the monoclonal antibody Alt-1 was deposited on November 23, 1999, at the American Tissue Culture Collection, 10801 University Blvd., Manassas, VA 20110-2209, and was given the ATCC accession number PTA-975. This deposit will be maintained under the conditions of the Budapest Treaty. All restrictions upon public access to the deposited material will be irrevocably removed upon the grant of a patent of this application.

Applicant submits that the claims are fully enabled and that the specification provides an adequate written description of the invention. Applicant respectfully requests reconsideration and withdrawal of the rejection.

35 U.S.C. § 112, first paragraph, scope of enablement

Claims 16-29 are rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly fails to enable the full scope of the claims.

Claims 19-20 and 24 have been cancelled, thereby obviating the rejection with respect to these claims.

The Examiner states at page 4 of the Office Action that "the specification, while being enabling for the use of Alt-1 to treat a tumor wherein the mammal generates an immune response that comprises an antibody that specifically binds to an epitope of tumor-associated MUC1 that is different from the epitope of tumor associated MUC1 that is specifically bound by Alt-1, does not reasonably provide enablement for the use of any binding agent ..." The Examiner additionally states at page 5 of the Office Action that "applicant has only shown that this can be achieved with Alt-1 as the agent."

Applicant respectfully disagrees. The claims have been amended to recite that the therapeutic composition comprises an antibody or antigen binding fragment. Claims 1, 16, and 18 have also been amended to recite that the antibody or antigen binding fragment thereof binds to an epitope to which a monoclonal antibody produced by a hybridoma having ATCC Designation Number PTA-975 specifically binds. Applicants have provided working examples for these antibodies (See the Examples).

As early as 1986, the Court of Appeals for the Federal Circuit has held that making monoclonal antibodies by the hybridoma process taught by Milstein and Kohler as well as screening methods to identify antibodies possessing certain desired characteristics was well known in the art and did not constitute undue experimentation for a person skilled in the art of antibodies. *See*, *Hybritech Inc., v. Monoclonal Antibodies, Inc.* 231 USPQ 81 (CAFC 1986).

Applicant asserts that the specification is fully enabled for administration of a therapeutic composition comprising an antibody or antigen binding fragment that binds to an epitope to

which a monoclonal antibody produced by a hybridoma having ATCC Designation Number PTA-975 specifically binds. Reconsideration and withdrawal of the rejection are respectfully requested.

35 U.S.C. § 112, second paragraph

Claims 2-3, 9-11, 13, 33 and 38 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

Claims 3, 13 and 38 have been cancelled, thereby obviating the rejection with respect to these claims.

(A) The Examiner states at page 6 of the Office Action that claims 2 and 9-11 recite the term "binding agent" which has no proper antecedent basis in independent claim 1. Applicant has amended claims 2 and 9-11 to address this issue.

(B) The Examiner states at page 6 of the Office Action that claim 13 is the same as claim 6. Applicant has cancelled claim 13, thereby obviating the rejection.

(C) The Examiner states at page 7 of the Office Action that claim 33 is improperly dependent from a claim recited after claim 33. Applicant has amended claim 33 to address this issue.

(D) The Examiner states at page 7 of the Office Action that claim 38 uses the term "activated". Applicant has cancelled claim 38, thereby obviating the rejection.

Statutory Double Patenting

Claims 35-36 are rejected under 35 U.S.C. § 101 as allegedly claiming the same invention as that of claim 1-2 of U.S. Patent No. 6,716,966. Applicant has cancelled claims 35-36, thereby obviating the rejection.

Non-Statutory Double Patenting

Claims 34 and 37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 6,716,966. Applicant has cancelled claims 34 and 37, thereby obviating the rejection.

35 U.S.C. § 102(b)

A. Claims 30-32, 34-35 and 37-38 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Spencer et al. (Cancer Letters, 1996, 100: 11-15).

Claims 30-32, 34-35 and 37-38 have been cancelled, thereby obviating the rejection.

B. Claims 30-32, 34-35 and 37-38 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Price et al. (Breast, 1993, Breast 2: 3-7).

Claims 30-32, 34-35 and 37-38 have been cancelled, thereby obviating the rejection.

C. Claims 30, 32-35 and 37-38 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Devine et al. (BioEssays, 1992, 14: 619-625).

The Examiner states at page 10 of the Office Action that Devine et al. disclose antibodies DF3, Mc1, Mc5, BrE1, HMFG-2, F36/22, B72.3, and SH1, which antibodies "have been used in therapeutic application [*sic*] to target and reduce tumor growth (see page 624, first column)."

Applicant respectfully traverses. Applicant has amended claim 33 to recite a therapeutic composition *consisting essentially of* an antibody or antigen binding fragment thereof that specifically binds to both soluble and tumor-bound tumor-associated MUC-1 and that is effective in therapeutically treating a mammal having a tumor that expresses a tumor-associated MUC-1. The specification teaches in Example 18 that patients were treated with naked (i.e., non-radiolabeled and non-conjugated) antibody. Thus, a therapeutic composition consisting essentially of Alt-1, for example, does not contain any other active ingredients that would exert a

therapeutic effect. Devine et al. teach antibodies used as a delivery agent to deliver a radiolabel, drug, or toxin (therapeutic agents), wherein patients responded favorably to treatment with radiolabeled antibodies (see left column of page 624). At no point does Devine et al. teach or suggest that a naked antibody or antigen binding fragment thereof has a therapeutic application in the absence of the radiolabel or immunoconjugate.

Claims 30, 32, 34-35 and 37-38 have been cancelled, thereby obviating the rejection with respect to these claims. Applicant asserts that claim 33 is novel over the teachings of Devine et al. and respectfully requests reconsideration and withdrawal of this rejection.

35 U.S.C. § 103(a)

Claims 38-41 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Devine et al. (BioEssays, 1992, 14: 619-625) in view of WO 98/33470 and Spencer et al. (Cancer Letters, 1996, 100: 11-15) or Price et al. (Breast, 1993, Breast 2: 3-7).

Claims 38-41 have been cancelled, thereby obviating the rejection.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945, under Order No. AREX-P03-002.**

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Respectfully Submitted,

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